

- Please keep your microphone muted
- Questions during the session? Please use the chat box. We will address the questions in the second part of the webinar
- Note that this webinar will be recorded and made available on our IHE-Europe <u>YouTube channel</u>
- Slides will be sent to you by email early next week





The IHE Methodology

...and how we're leveraging it on the UNICOM project.

Derek Ritz, IHE member in UNICOM project 10 November 2023 IHE-Europe Monthly Webinar



Agenda for this webinar

- Quick introduction
- What is IHE's role in the digital health SDO community?
- What is the IHE Methodology (and why it is helpful)?
- How are we trying to make UNICOM more boring?
- o Q&A



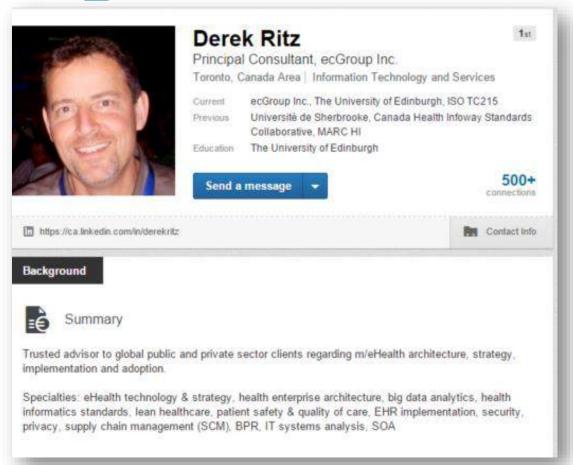


Compulsory apologies...



Introduction

Linked in





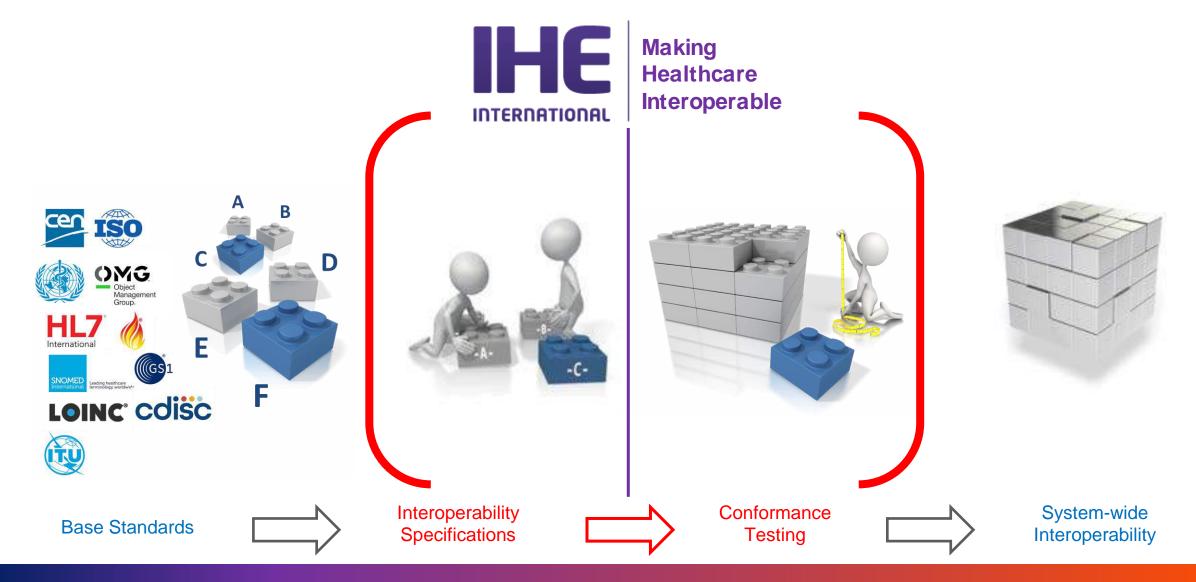


What role does IHE play in the digital health SDO ecosystem?





What role does IHE play in the digital health SDO ecosystem?





How does IHE play this role?



Domain Committees

Radiology
IT Infrastructure
Pharmacy
Quality, Research & Public Health

Cardiology

Devices

Eye Care

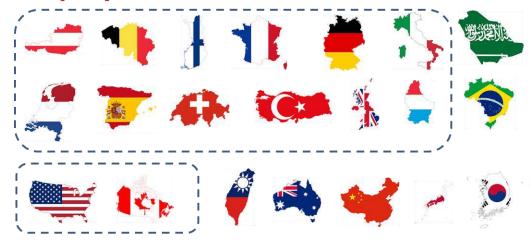
Dental

Pathology and Laboratory Medicine Radiation Oncology Patient Care Coordination Dental

Create engineering artefacts.

Making Healthcare Interoperable

Deployment Committees



Nationalize artefacts.
Conformance-test.
Exert governance.





ADA

COLLEGE of AMERICAN PATHOLOGISTS

MACP AAMI

AMERICAN COLLEGE of CARDIOLOGY

JAHIS 保健医療福祉情報システム工業会 25



What is the **value proposition** behind all this **boredom**?

Scale is the innovation.



Maybe we at IHE should change our marketing "tag line"...



Taking all the *fun* out of digital health for over 20 years.





How does the IHE Methodology accomplish this?





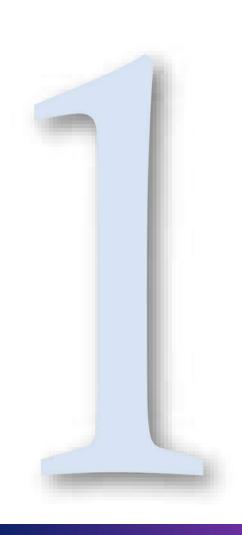
There are **three** key pillars to the Methodology.



- IHE **Profiles** (implementable actor-transaction specifications)
- 2 IHE reference models (technical frameworks defined in Gazelle)
- 3 IHE conformance assessment (testing events)



IHE Profiles follow a prescriptive **format** and **governance** process.





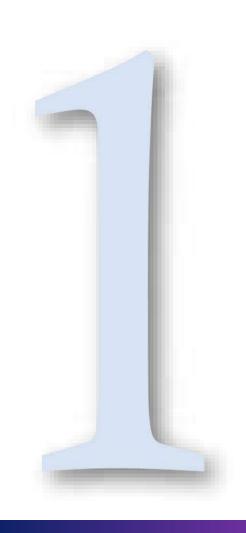
Volume 1:

Volume 2:

Volume 3:



In Volume 1, business requirements are clearly and simply described.





Volume 1:

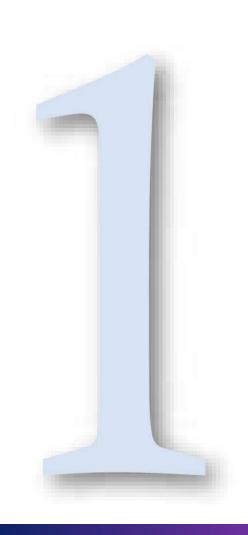


Volume 2:

Volume 3:



Use cases are described in terms of actors and their interactions.





Volume 1:



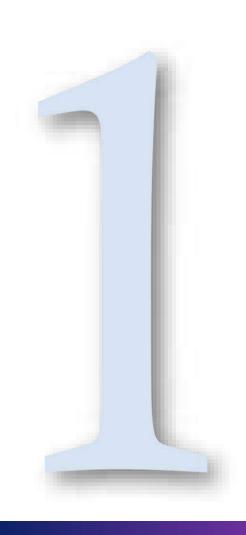


Volume 2:

Volume 3:



If existing IHE actors are applicable, these are named.

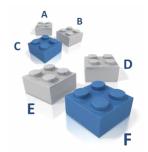




Volume 1:





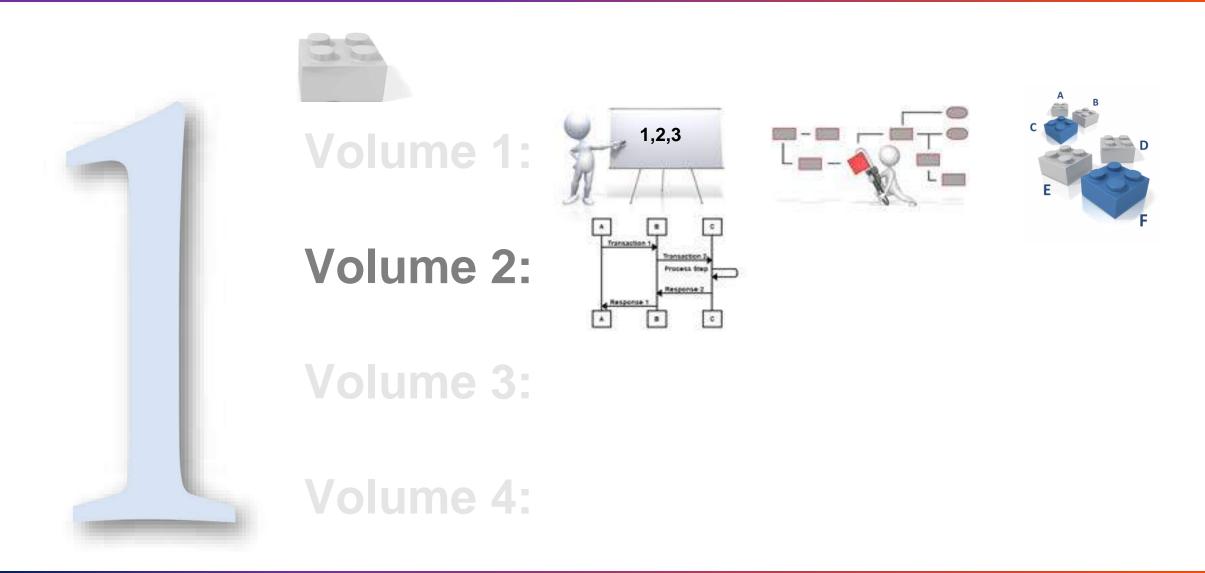


Volume 2:

Volume 3:

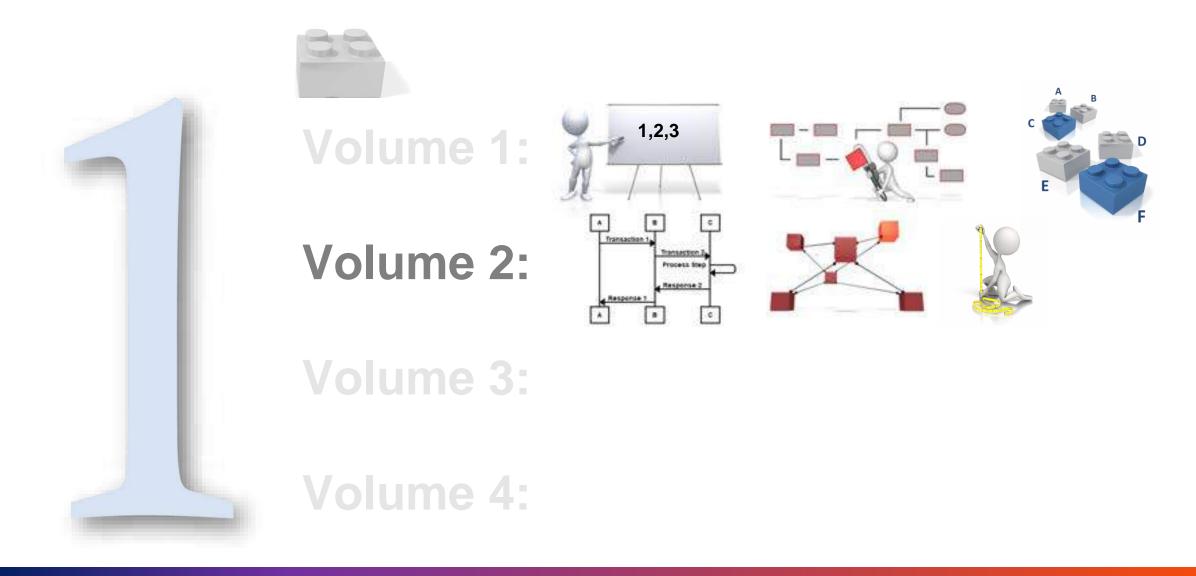


In Volume 2, the actors' transactions are normatively defined.



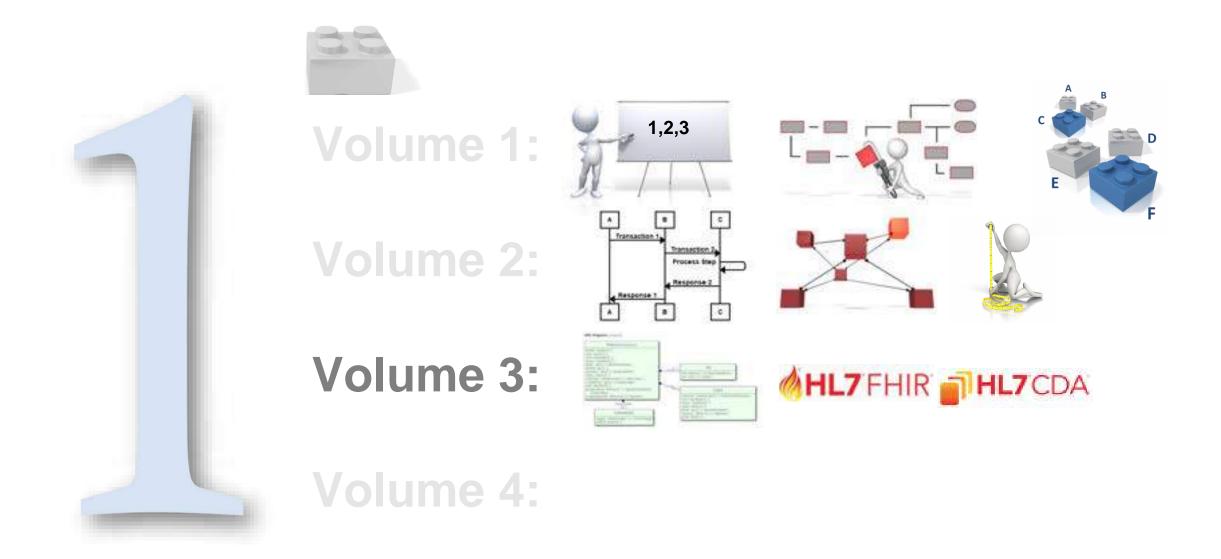


Unambiguous engineering supports interoperability and testability.



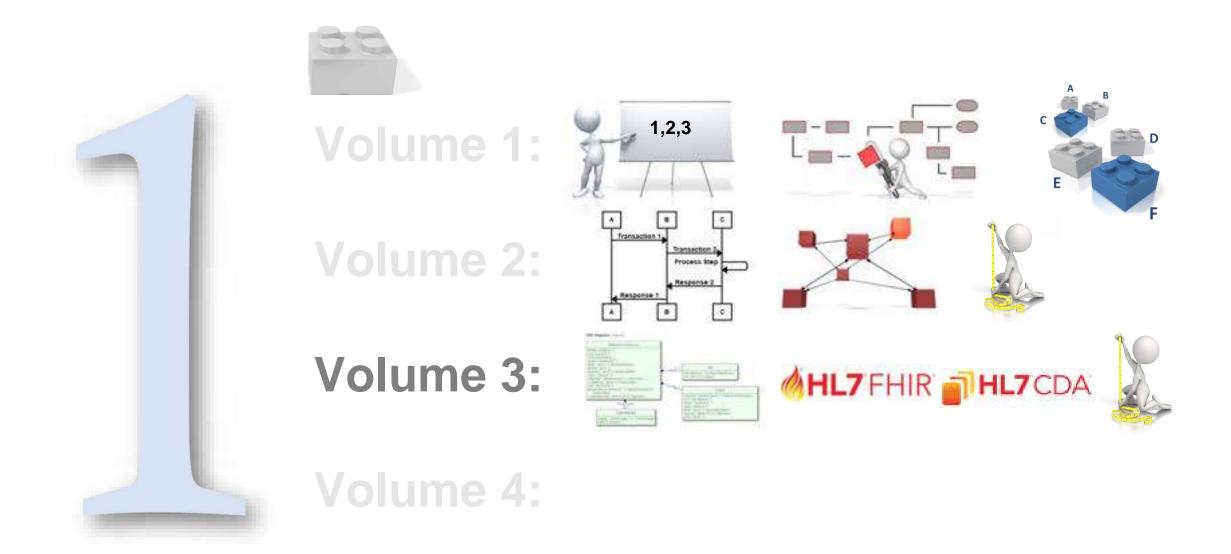


In Volume 3, content data models are normatively defined.



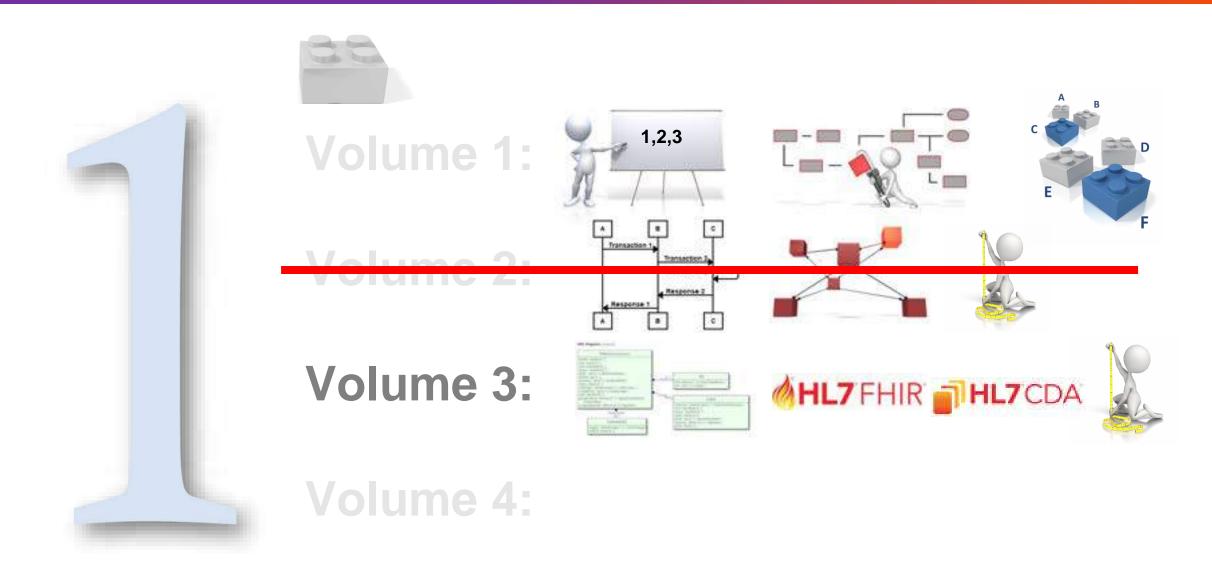


These content models are also **testable**... the **optionality** is removed.



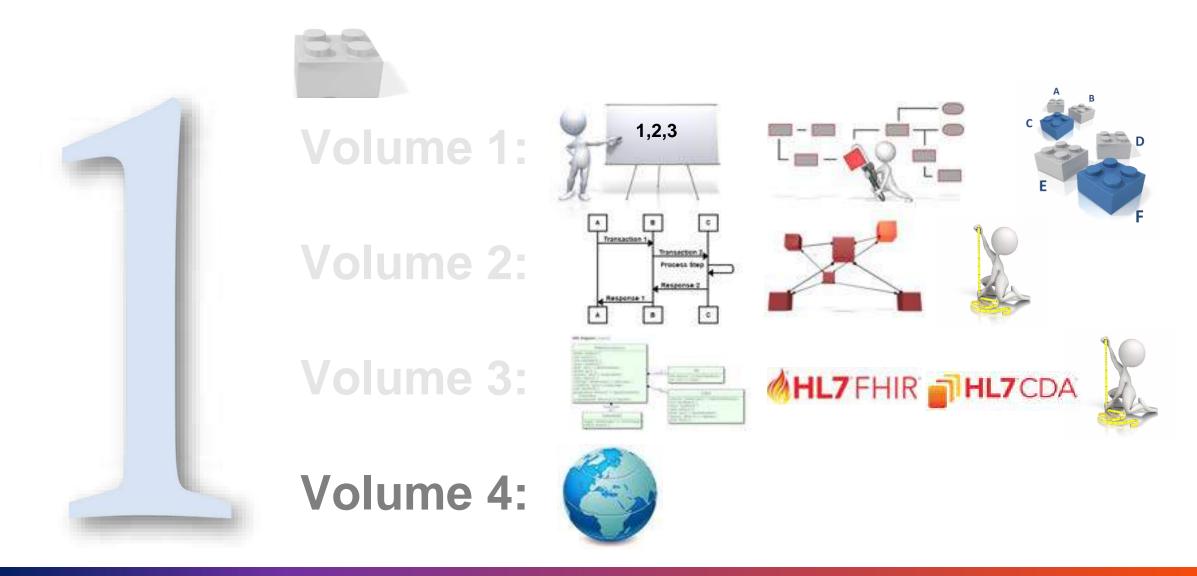


It is possible to have a **content-only** Profile.



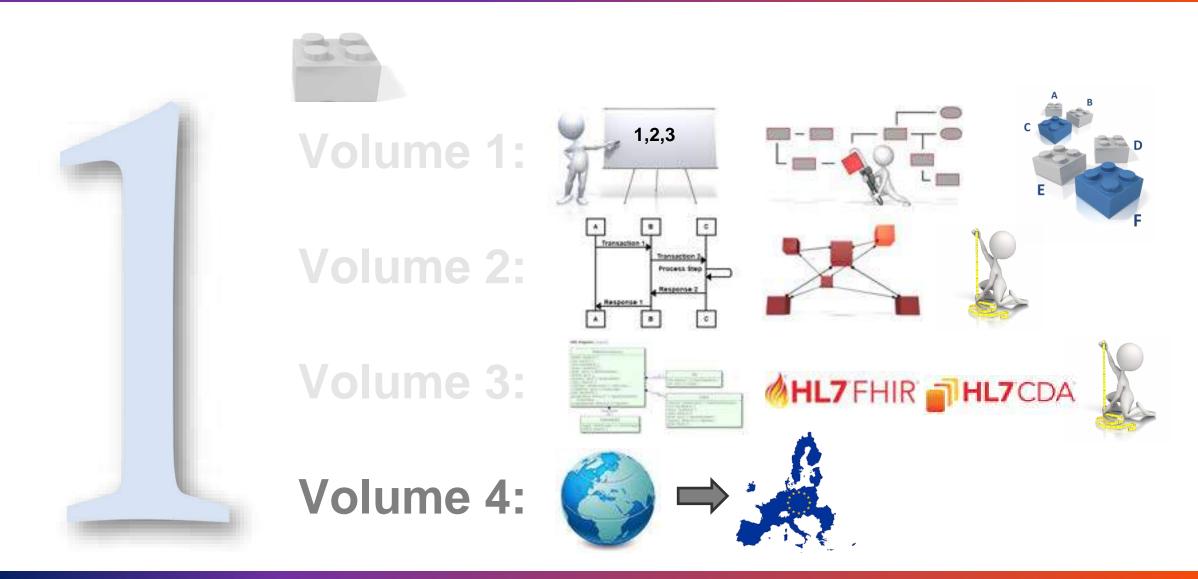


IHE Profiles are **global** artefacts. They are **specialized** in Volume 4.



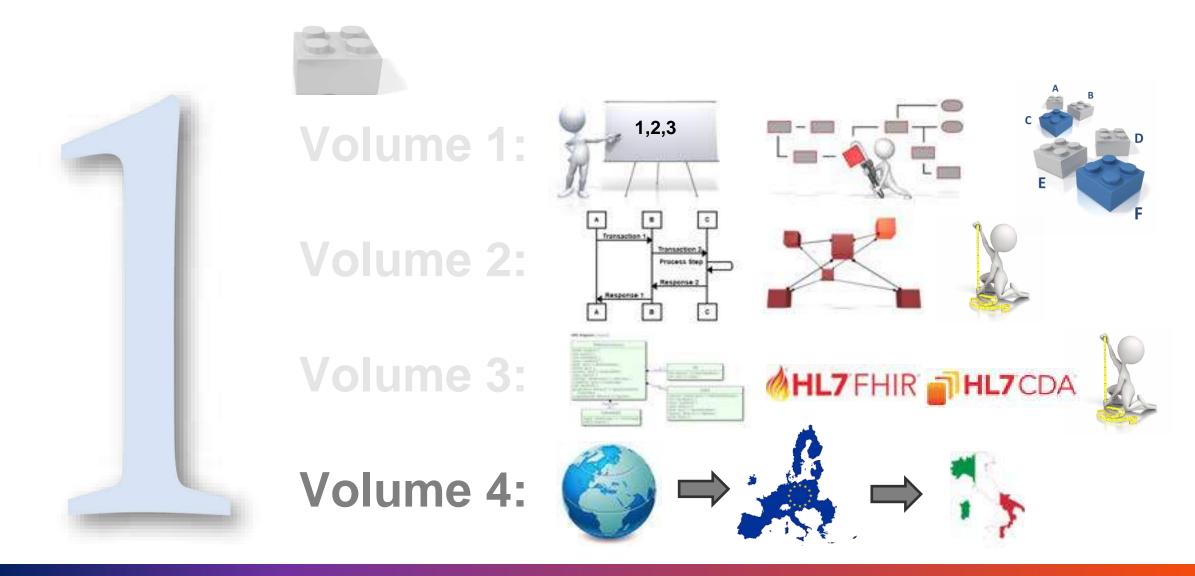


Regional constraints can be defined, here.



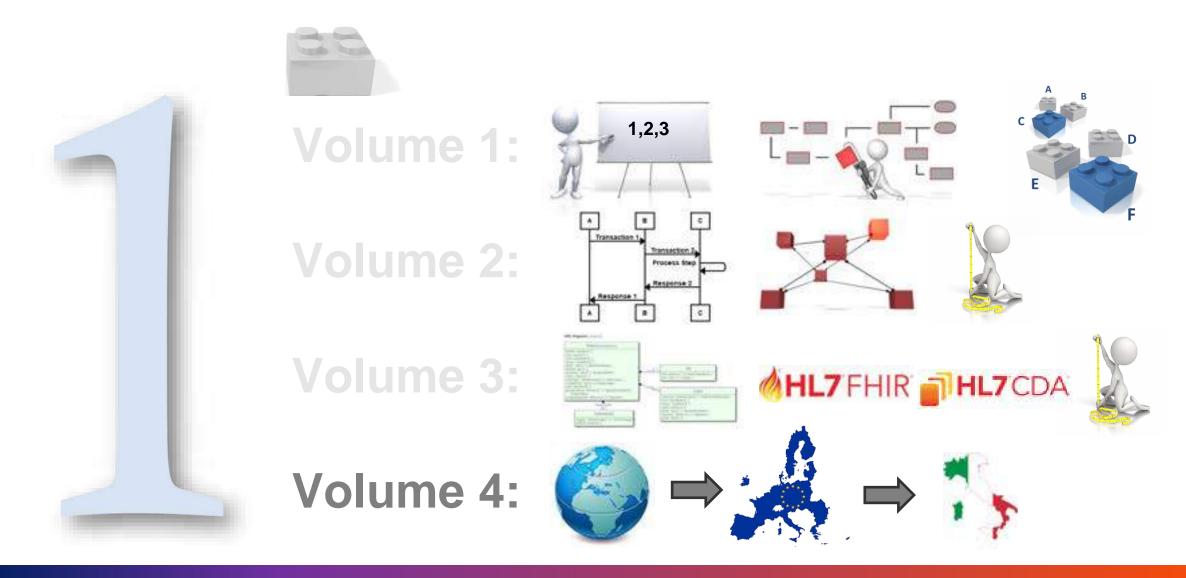


And so can national ones.





Each relevant IHE **Deployment** Committee *governs* their Volume 4 content.



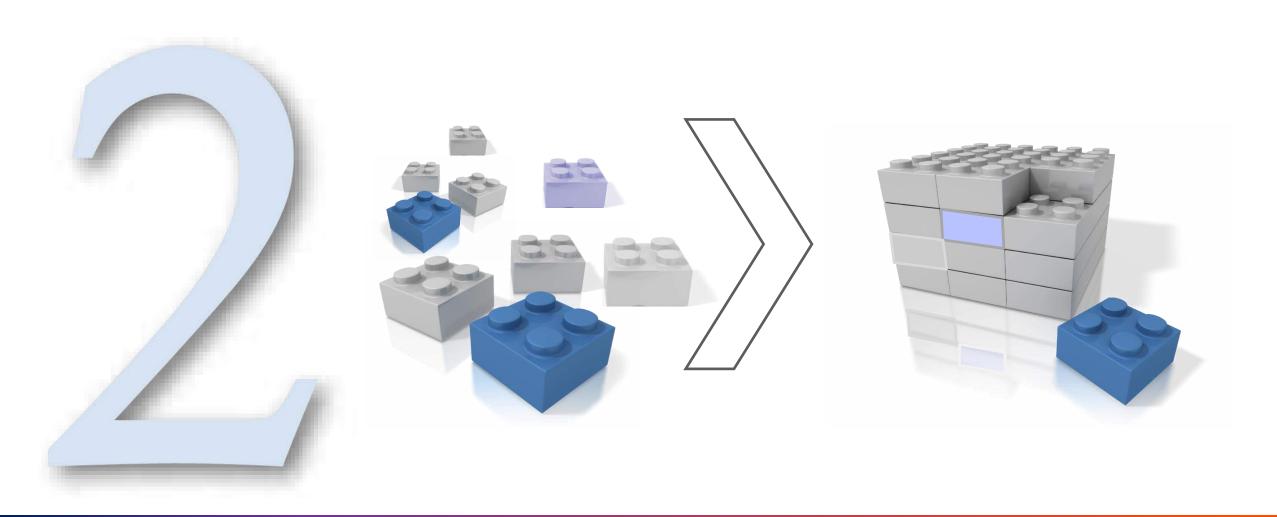


Pillar 2 is **reference models**. These are built from **IHE Profiles**.



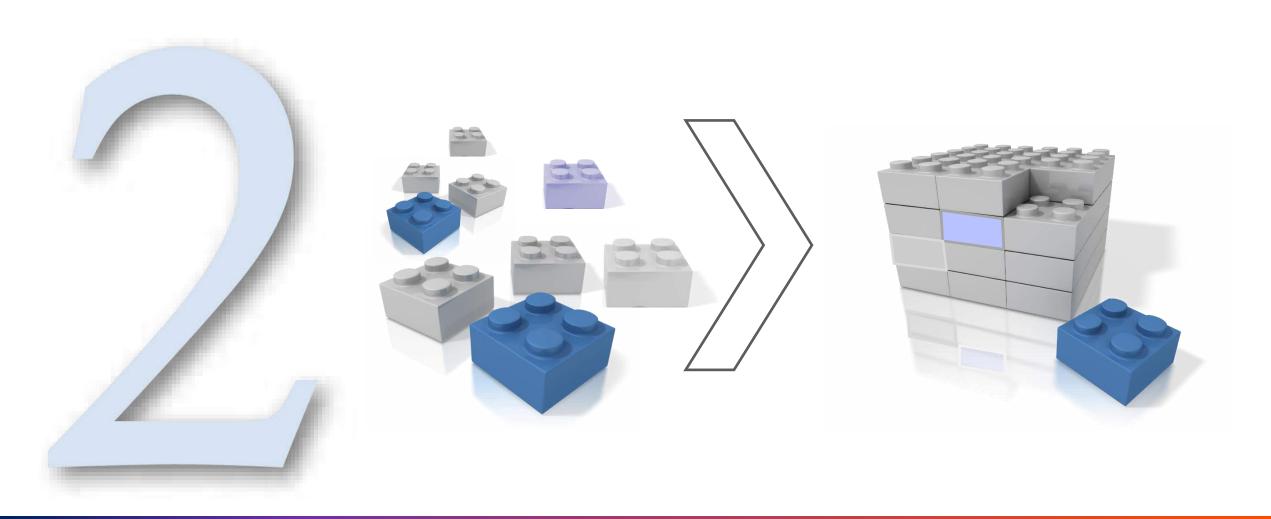


The models can be thought of as assemblies of Lego® blocks.





Their **boringly** engineered dimple patterns means blocks **fit** together.



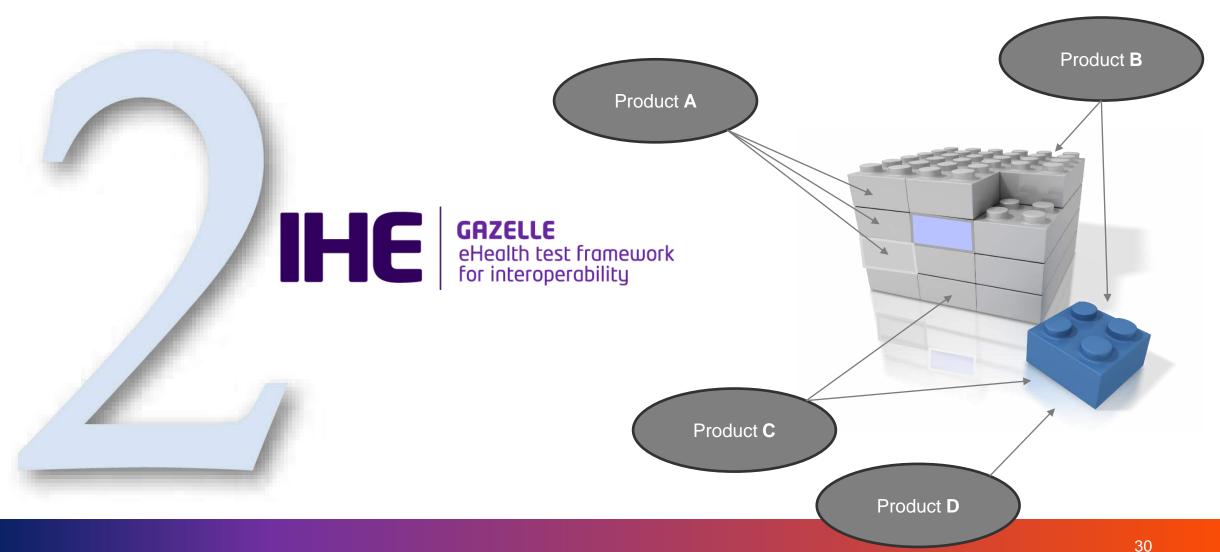


The **reference models** are described in **IHE Gazelle**.



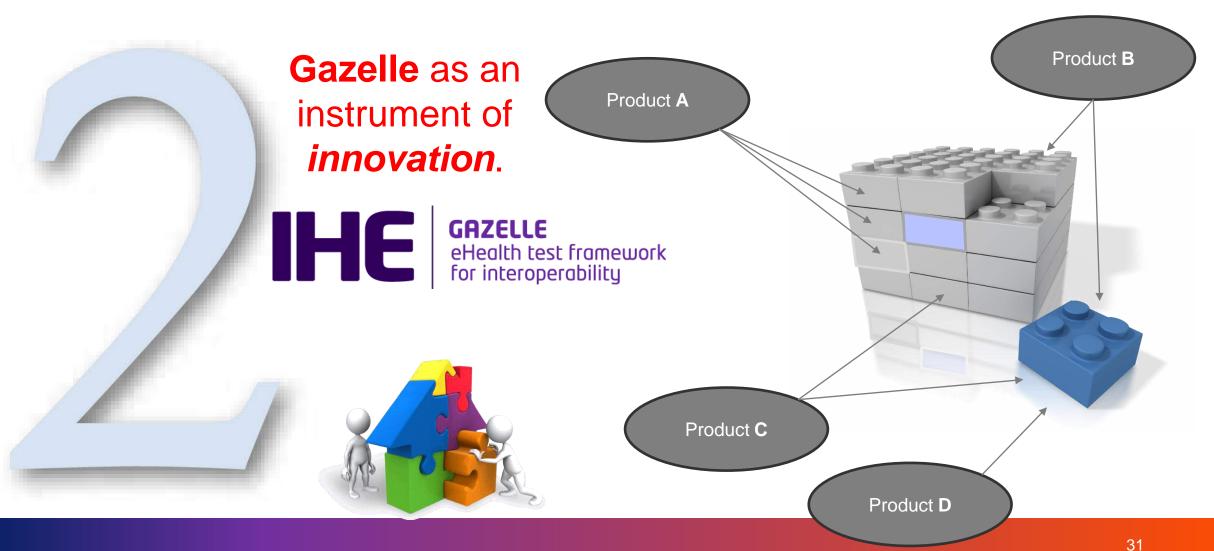


Software solutions operationalize one or more building blocks.



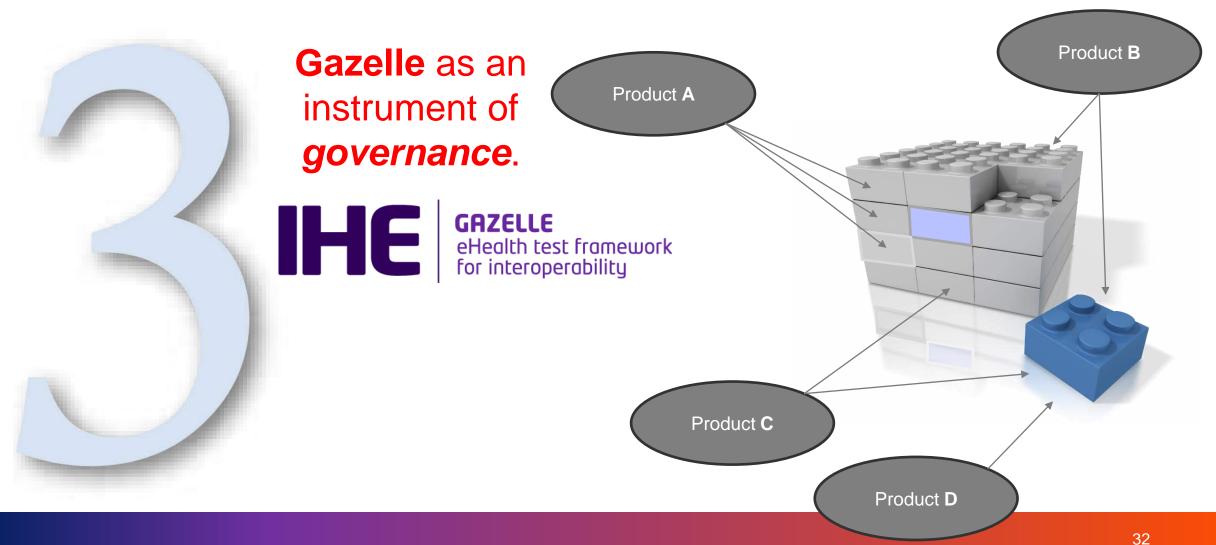


Engineering events can be leveraged to iterate the reference models.





Pillar 3 takes these events a further step – to conformance testing.





Products that pass the tests "fit" with the framework.



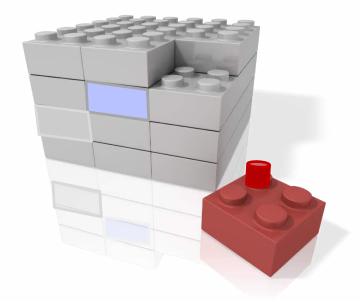


Products that are **non-conformant** are identified and told what to **fix**.



Gazelle as an instrument of **governance**.

GAZELLE
eHealth test framework
for interoperability





This process ensures **conformant** solutions **plug-and-play**.





Summary points







- IHE's role in the SDO ecosystem is to support going to scale. We do that by making "exciting" things boring.
- The IHE Methodology is leveraged to develop IHE Profiles. These are like Lego® blocks. They can be assembled into a reference model to address a particular use case or set of use cases.
- Gazelle can be employed as an instrument of *innovation* to **iterate** the reference model design at **engineering** events. It can also be employed as an instrument of **governance** to **conformance test** digital health solutions' adoption of and operationalization of the Profiles.

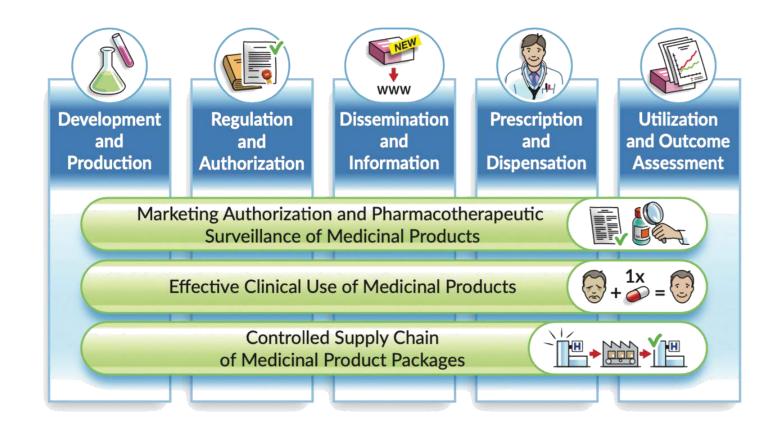


How are we making UN/COM more boring?





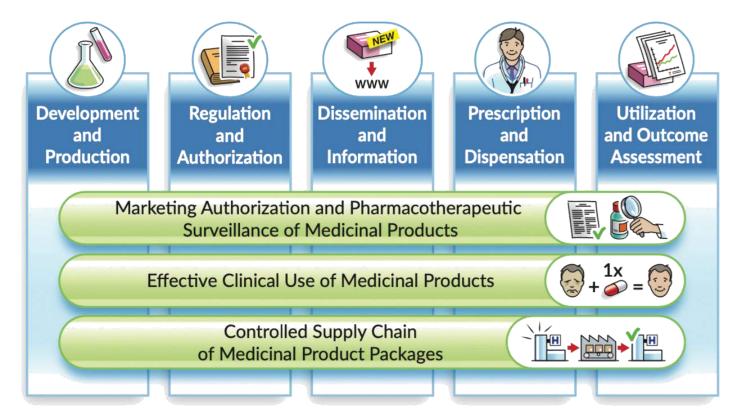
UNICOM is a European initiative to adopt the **IDMP** standards.



It is a big, **complicated** project. There are a **lot** of stakeholders. They are doing a **lot** of things. It **isn't** boring.



Our role in UNICOM is focused on the TEST LAB.

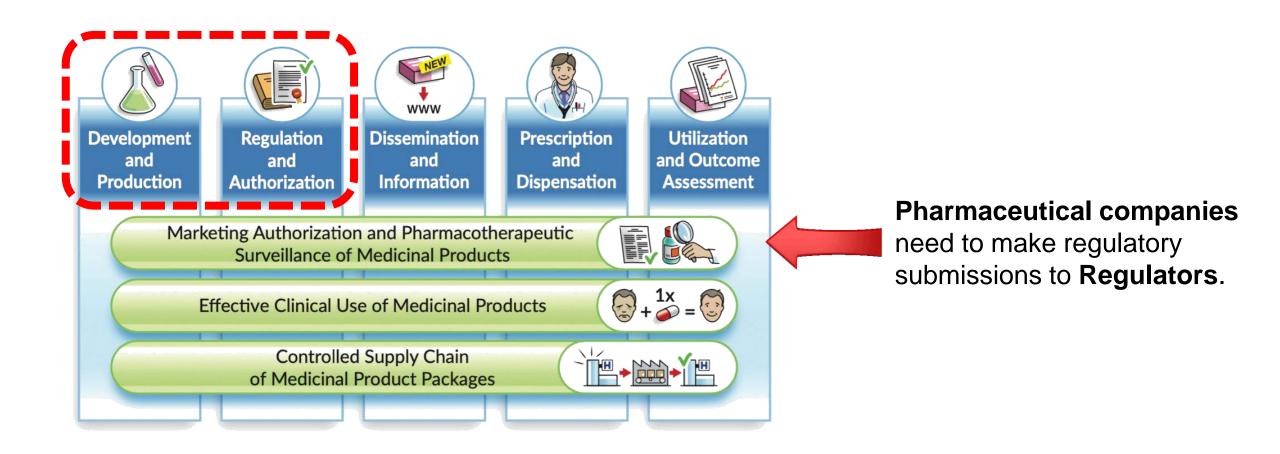




All of the workflows need to be tested. But there many practical things to figure out *before* we can begin testing.

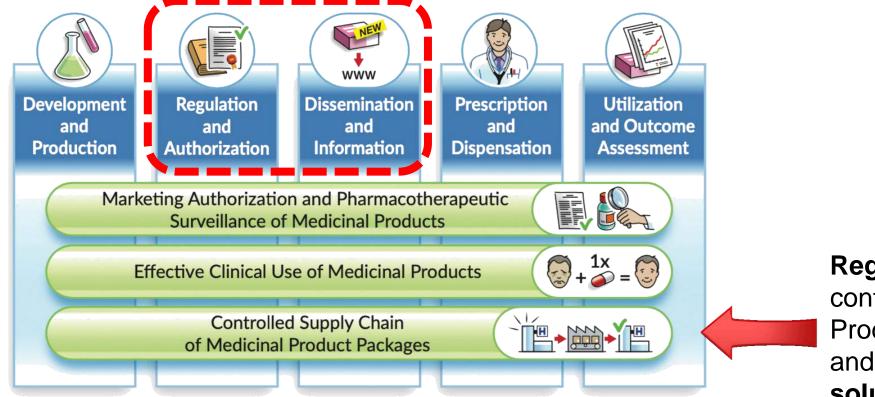


Multiple, different data exchange pipelines are in play.





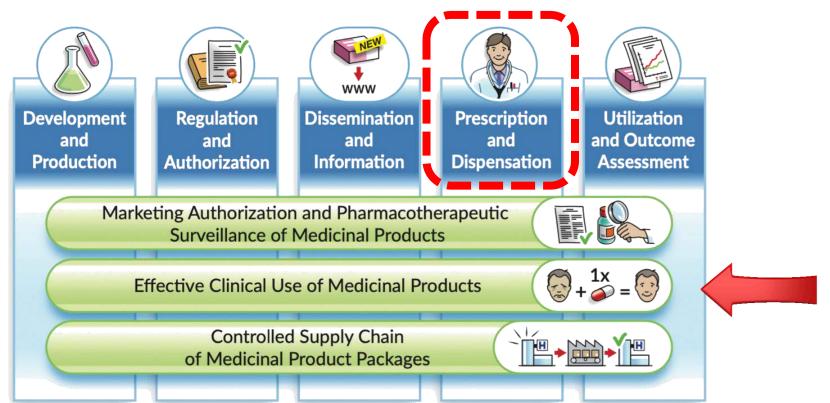
Multiple, different data exchange pipelines are in play.



Regulators need to publish content to national Medical Products Dictionaries (MPDs) and onward to digital health solution users.



Multiple, different data exchange pipelines are in play.





Prescribers & Dispensers need to leverage IDMP-adherent data sets to support safe medicinal workflows... including across borders.



We tried to string together the multiple pipelines...



...it's down here at the bottom.



We included actors across all the UNICOM stakeholders.

National digital health agency in Country-B National digital health agency in Country-A MPD governance authority in Country-A MPD governance authority in Country-B Pharmaceutical Company's Database European Medicines Agency (EMA) Provider-A's digital health solution Provider-B's digital health solution Patient-centric EHR in Country-A Patient-centric EHR in Country-B Patient (domiciled in Country-A) Patient 's personal health app NCA-A's Database Systems Care Provider in Country-B Care Provider in Country-A NCPeH in Country-B NCA-B's Database NCA in Country-B NCA in Country-A NCPeH-B



Industry

EMA

NCAs

MPDs

We included both **systems** and **humans**.

National digital health agency in Country-B National digital health agency in Country-A governance authority in Country-A Pharmaceutical Company's Database (EMA) Provider-A's digital health solution Provider-B's digital health solution Patient-centric EHR in Country-B Patient-centric EHR in Country-A Patient (domiciled in Country-A) Patient 's personal health app governance authority in **European Medicines Agency** NCA-A's Database Systems Care Provider in Country-B Care Provider in Country-A Pharmaceutical Company **EMA's SPOR databases** NCPeH in Country-A NCPeH in Country-B NCA-B's Database MPD in Country-A NCA in Country-B NCA in Country-A MPD MPD NCPeH-A NCPeH-B

National Digital Health Agencies

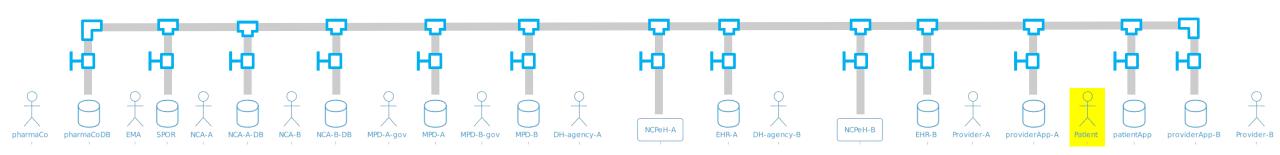
Care Providers & Patients



We refer to our metaphor as the "UNICOM data pipeline".



Our distinct UNICOM stakeholders and their systems are interconnected. Each has an "upstream" data provider and a "downstream" data consumer. Together, they form a data pipeline that supports UNICOM's use case workflows.

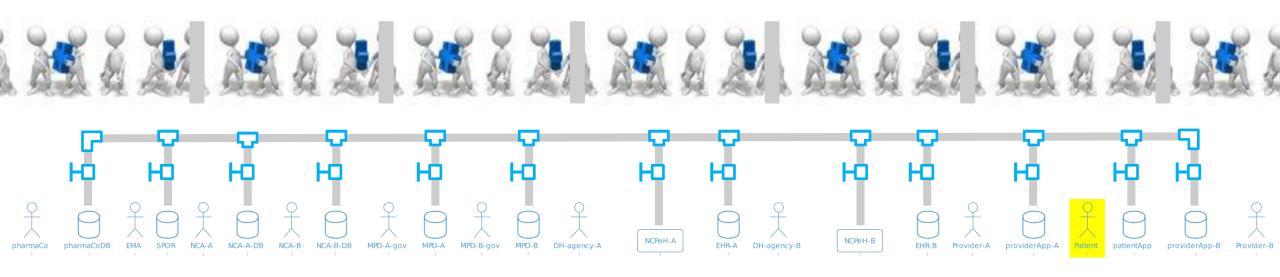




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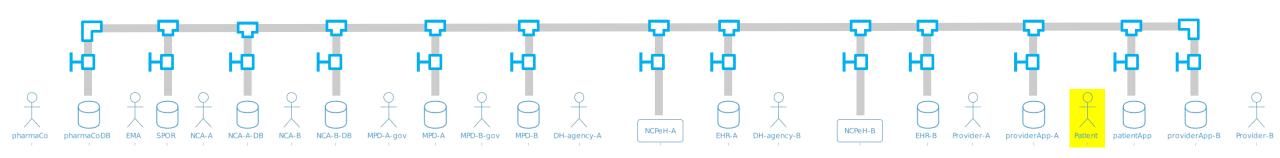
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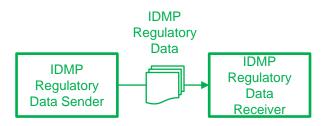
This metaphor gives us a way to see how our stakeholders' workflows connect together to "make UNICOM go".





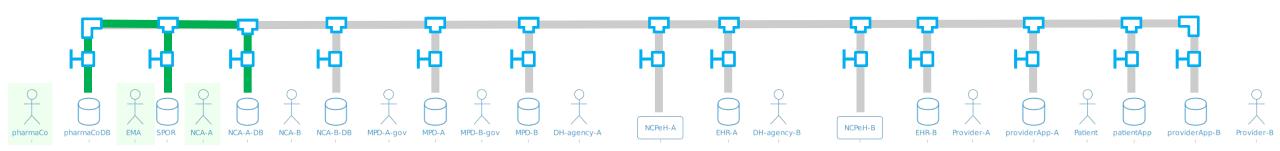


Receiving Medicinal Product Data



INPUT-to-Regulator:

- Pharma Company submissions to EMA, or to an NCA
- Content feeds from EMA to NCAs



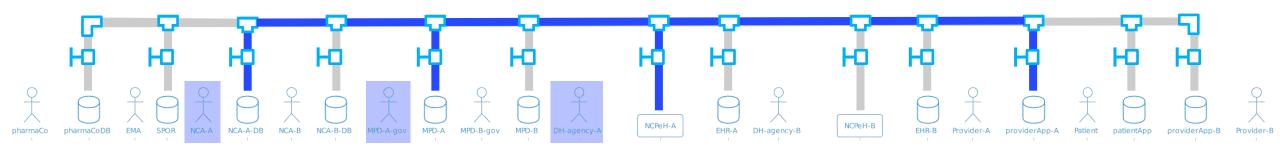


Sharing Medicinal Product Data



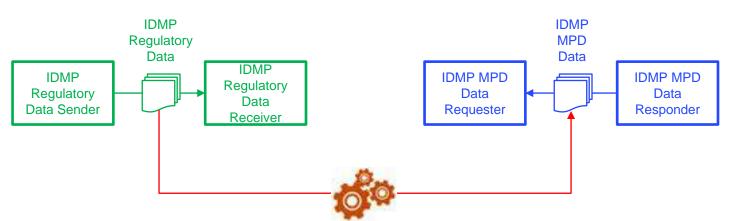
OUTPUT-from-Regulator:

- Content feed from NCAs to MPD operators
- Content feed from NCAs to NCPeH operators
- Content feed from MPDs to eHealth solutions

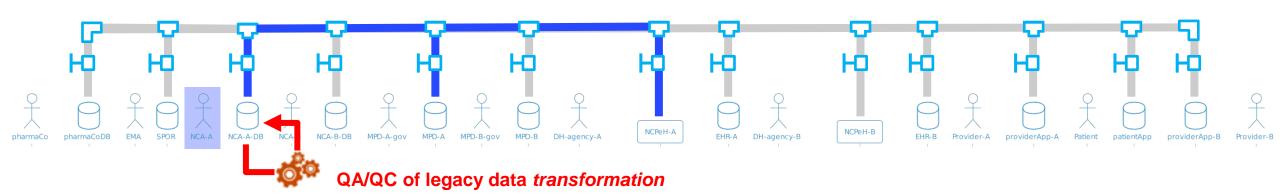




Managing Medicinal Product Data

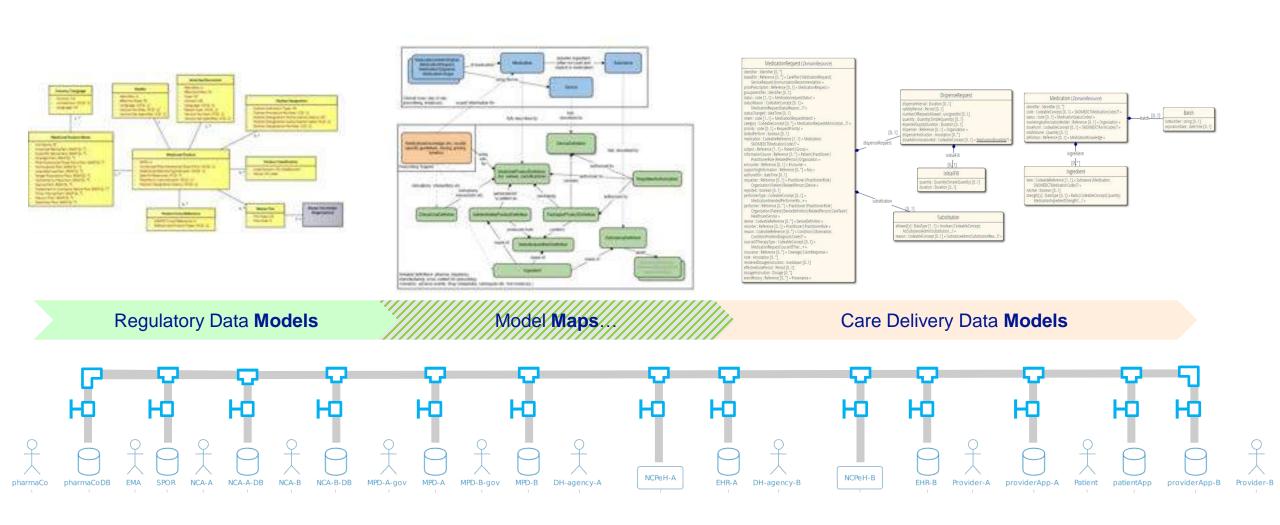


Mapping from a *regulatory* data model to a *care delivery* data model.





We see the importance of mapping from regulatory to clinical models.



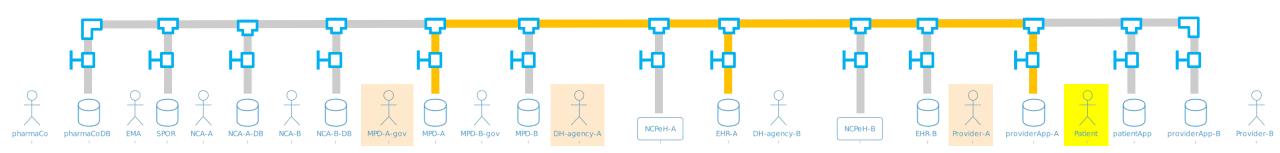


Prescribing a Medicinal Product



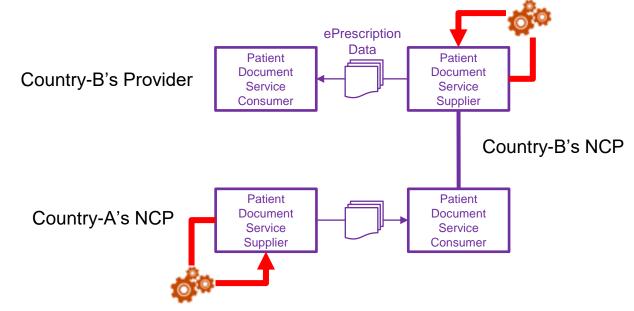
Create an ePrescription:

• Provider submits an MPD-adherent ePrescription to the "local" (Country-A) EHR

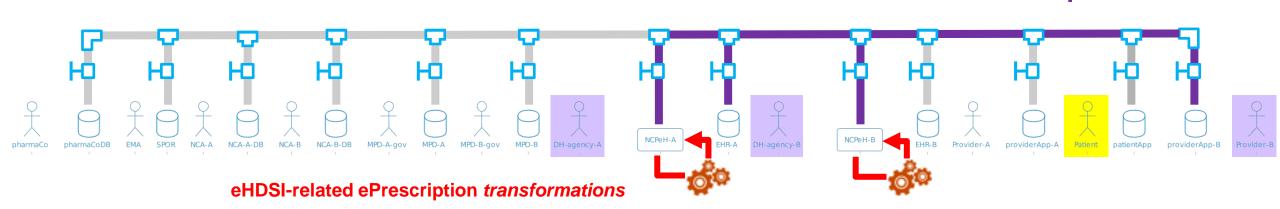




Retrieving a cross-border ePrescription

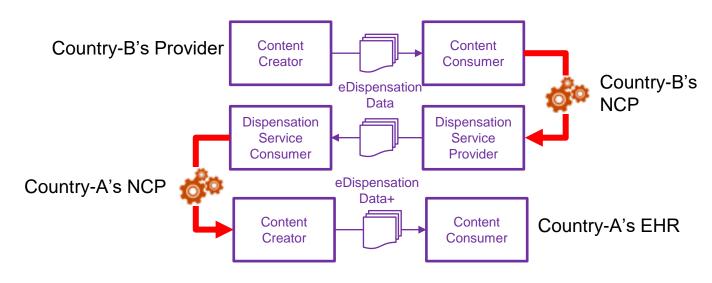


Cross-border Retrieve of ePrescription



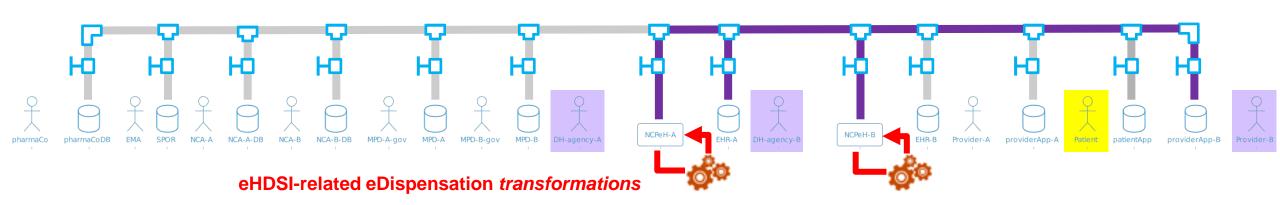


Sharing a cross-border eDispensation



Create an eDispensation:

Provider submits an adherent eDispensation to NCPeH-B (➡ NCPeH-A➡ EHR-A)





Our IHE-supported UNICOM TEST LAB provides important value.

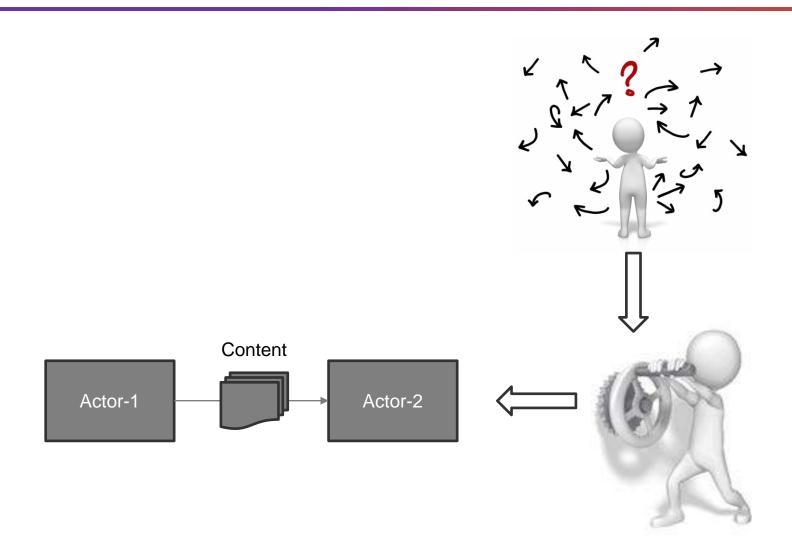
Innovation Implementability

Governance





At each step, we leverage the **IHE Methodology** to make things **less fun**.





Our work has involved a lot of convening and coordinating...





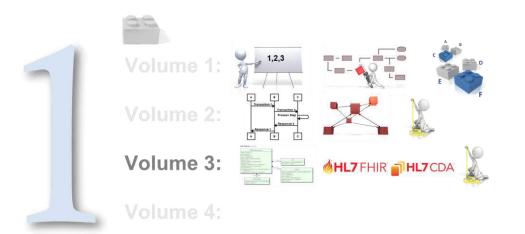


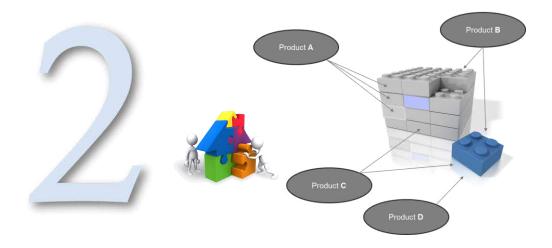


We leveraged an IHE-based document format to help TEST LAB partners develop well-formed use case descriptions. We used a checklist to assist them in following helpful formalisms. These boring practices allow stakeholders to readily see how their use cases fit together as part of the overall UNICOM data pipeline.



...and a lot of practical **prototyping** and **experimenting**...







IHE teammates developed example **specifications**, and even prototypical **servers**, that could support teams **exploring** interoperability use cases in a "lab" environment. The lessons learned have been **invaluable**.



...with testing, too, where the specs are already mature...

Some of the UNICOM use cases leverage **normative** EU specifications based on **mature** IHE profiles. Where an eHealth Digital Service Infrastructure (**eHDSI**) Lego® block needs to be tested... we have the tools, in hand, to do it.







... and with the goal of making UN COM more boring, every day.





We could take the fun out of a bouncy castle.







Join us for the December webinar: 8 Dec 1PM CET





Register here:



15/12/2022 63